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Tantalum Beads

510(k) Summary

Common/Usual Name: Radiographic Marker

Proprietary Name: Tantalum Beads – Radiographic Marker

Classification Name: Staple, Implantable - Product Code: GDW (878.4750)
Staple, Fixation, Bone, Metallic – Product Code: NDM (888.3030)

Device Classification: GDW - Class II
NDM – Class II, exempt

Sponsor:
Biomet, Inc.
56 East Bell Drive
Warsaw, Indiana 46580
Establishment Registration Number: 1825034

Contact Person:
Lonnie Witham
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Telephone no. (219) 372-1510
FAX No. (219) 372-1683
E-mail address: lonnie.witham@biometmail.com

The product will be packaged, and distributed from Biomet Inc. headquarters in Warsaw, Indiana.

Performance Standards: To the best of our knowledge, no performance standard has been established under Section 514 for this device.

Device Description: Tantalum beads are spherical, 0.8 MM diameter, X-ray markers made of commercially pure, unalloyed tantalum. The beads are provided sterile in packages of eight. Tantalum beads are used as radio-opaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an X-ray. They are used in conjunction with total joint replacement, soft tissue repair, and bone fractures. The beads are applied with manual surgical instruments. **Refer to Exhibit A for engineering drawing.**

Sterilization Information: Devices are provided sterile by radiation methods as follows:
Radiation Type: Gamma
Radiation Source: Cobalt 60
Minimum Dosage: 25 kGy
Maximum Dosage: 40 kGy
Sterility Assurance Level: 10^{-6}
Sterility Validation Method: AAMI/ ISO11137, Method 1

6. INTENDED USE OF THE DEVICE

Tantalum beads are used as radiopaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an X-ray. Implant surgery associated with the use of radiographic markers may include total joint replacement procedures, soft tissue repair, and bone fracture fixation procedures.

7. STATEMENT OF COMPARISON OF TECHNOLOGICAL FEATURES

Both the new and predicate devices consist of non absorbable material (stainless steel, titanium, tantalum) listed in the FDA's Biomaterials Compendium and list of FDA recognized standards. The predicate devices are implanted into breast soft tissue during open or percutaneous procedures to radiographically mark the surgical location. The tantalum bead radiographic markers are implanted in soft tissue or bone during orthopedic procedures to radiographically mark the relative location of an implant. The metallic materials and intended use as radiographic markers are technically equivalent.

8. CONCLUSIONS

The use of the UltraClip Tissue Marker, the Micromark Clip, and Tantalum Beads as radiographic markers are substantially similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 3 2001

Mr. Lonnie Witham
Regulatory Affairs
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K010348
Trade Name: Tantalum Beads - Radiographic Marker
Regulation Number: 878.4300
Regulatory Class: II
Product Codes: NEU, FZP
Dated: March 2, 2001
Received: March 6, 2001

Dear Mr. Witham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K010348

Device Name: Tantalum Beads (radiographic markers)

Indications for Use:

Tantalum beads are used as radiopaque markers and may be implanted into bone or soft tissue. These devices are used to measure movement of implants after surgery with the aid of an X-ray. Implant surgery associated with the use of radiographic markers may include total joint replacement, soft tissue repair, and bone fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ (Per 21 CFR 801.109) OR Over-The-Counter-Use _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010348